REMARKS:

Applicant has carefully studied the nonfinal Examiner's Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Claim Rejections – 35 U.S.C. § 103

Applicant acknowledges the quotation of 35 U.S.C § 103(a).

Claims 1-5, 9, 10 and 12 stand rejected under 35 U.S.C § 103(a) as being unpatentable over Giger et al. (U.S. 5,133,020) in view of Huo et al. (U.S. 6,282,305).

Regarding claim 1, the Office states that Giger et al. teaches identifying a standard threshold of the computer algorithm for identifying false positive abnormalities (column 6, lines 33-column 9, line 10); and adjusting the threshold for identifying false positives based on the risk associated with a patient (column 12, line 58-column 13, line 7). The Office goes on to state that while Giger et al. does not specifically teach calculating breast cancer risk, that Huo et al. discloses a method which includes establishing a risk probability with a patient with factors such as age (column 5, lines 55-63; column 6, lines 25-40); applying a computer algorithm to find abnormalities in a patient's mammogram (column 9, lines 30-48). The Office concludes that it would have been obvious for one of ordinary skill in the art at the time the invention was made to combine the references of Huo et al. with Giger et al. to gain the benefit of using known risk analysis methods to improve the prognosis or diagnosis of breast cancer based on mammograms. Giger et al. indicates that the threshold may be adjusted for the risk assessment of a patient for better evaluation of a mammogram (column 12, line 58-column 13, line 7). Based on their recommendation, one of ordinary skill in the art would be motivated to search for a method of

calculating breast cancer risk. Huo et al. provides methods of calculating breast cancer risk. One of ordinary skill in the art would be motivated to combine the references of Giger et al. and Huo et al. in order to carry out Giger et al.'s method as he indicates.

Applicant respectfully traverses the finding of the Office.

Claim 1 has been amended to clearly state the method steps which applicant regards as the invention. Accordingly, claim 1 of the present invention includes the method steps of establishing a risk probability value associated with a patient, the risk probability value calculated from an array of risk factors associated with breast cancer, selecting a computer algorithm to identify abnormalities in a patient's mammogram, identifying a standard threshold of the computer algorithm for identifying false positive abnormalities, adjusting the standard threshold of the computer algorithm for identifying false positive abnormalities in response to the risk probability value associated with the patient and applying the computer algorithm using the adjusted standard threshold to identify abnormalities in the patient's mammogram.

The present invention relates to screening mammograms. By contrast, Giger et al. relates to diagnostic mammograms. It is known in the art that a screening mammogram is an x-ray of the breast used to detect breast changes in women who have no sign or symptoms of breast cancer. By contrast, a diagnostic mammogram is an x-ray of the breast that is used to check for breast cancer after a lump or other sign or symptom of breast cancer has been found. The present invention is a method of screening mammograms to identify abnormalities in mammograms of women who have no other signs or symptoms of breast cancer.

Giger et al. describes a diagnostic method for analyzing mammograms whereby lesions are classified as either malignant or benign based on border fluctuation pixel data. The cutoff value described by Giger is used to classify a lesion as being either malignant or benign. Lesions having a positive value for the normalized size difference could be considered malignant. Each lesion is then classified depending on its relationship to the predetermined cutoff value. The cutoff value is described as being adjusted based on the patient's risk for breast cancer. As such, Giger describes using a cutoff value to classify previously identified abnormalities as being either malignant or benign. Such a cutoff value can then be adjusted to be more or less sensitive to the border fluctuations of the lesions.

By contrast, the present invention is a method of screening mammograms for abnormalities which utilizes a cutoff value in the identification of abnormalities from a mammogram, not in the classification of previously identified abnormalities as being either malignant or benign. As claimed, the present invention adjusts a standard threshold of a computer program adapted to find abnormalities in a patient's mammogram in response to a risk probability value associated with the patient. When a subject has a high risk of breast cancer, the false positive rate (acceptance) should be increased so that a suspicious mammograms or suspicious areas within a mammogram may be detected; this will increase the true positive sensitivity or decrease the true positive error rate. Likewise for low risk subjects, the false positive rate (or tolerance) can be lowered; this will increases the specificity while not infringing on the true positive detection rate. This defines risk based primary detection. As such, the sensitivity adjustment in accordance with the present invention is related to the identification of abnormalities in a mammogram. This is not equivalent to Giger et al. who describes a sensitivity adjustment related to the classification of previously identified abnormalities as being either malignant or benign.

In summary, the work by Giger et al. analyzes abnormalities and describes a classification scheme. In this scheme the classification thresholds may be based on the patient's risk in deciding if the abnormality is benign or malignant. By contrast, in the present invention application, the primary detection may be based on risk. The present invention does not attempt to classify a predetermined abnormality based on risk, but instead applies risk based thresholds to find the abnormalities within a mammogram or find mammograms that should be scrutinized more carefully by some other means. The work by Giger et al. describes the secondary classification task once an abnormality is detected in contrast to the present invention which describes risk based primary detection.

For the reasons cited above, Giger does not teach identifying a standard threshold of a computer algorithm for identifying false positive abnormalities and adjusting the threshold for identifying false positives based on the risk associated with a patient. As such, combining the references of Huo et al. with Giger et al. would not result in the present invention as disclosed and claimed.

For the reasons cited above, Applicant believes that amended independent claim 1 is not obvious in view of Giger et al. in combination with Huo et al., and is therefore believed to be in condition for allowance.

Claims 2-13 are dependent upon claim 1, and are therefore allowable as a matter of law.

Claim 14 is new.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned is requested.

Very respectfully,

SMITH & HOPEN

By:_____

Dated: January 8, 2007
Reg. No.: 46,457

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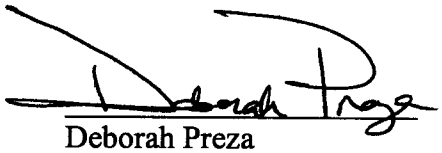
CERTIFICATE OF ELECTRONIC TRANSMISSION

I HEREBY CERTIFY that this Amendment AF is being electronically transmitted through EFS-Web to the United States Patent and Trademark Office, Art Unit 1631, Attn.: Jerry Lin on January 8, 2007.

Dated: January 8, 2007



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